

Applicant : Jihad A. Mustapha
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Remarks:

The amendments and remarks presented herein are believed to be fully responsive to the Office Action dated October 6, 2006, the period for response being extended to February 6, 2007 via the enclosed petition and fee for a one month extension of time.

Attached is a new Power of Attorney and Revocation of Prior Power authorizing the undersigned to file this Response. Please change the correspondence address to Van Dyke, Gardner, Linn & Burkhart, LLP at the address noted on the attached Power of Attorney.

Claims 1-8 and 10-23 are pending in the application. Claim 9 has been canceled herein without prejudice and claims 1-6 and 8 have been amended as set forth above. New claims 10-23 have been added. The amendments and new claims are fully supported in the specification and drawings as originally filed. No new matter has been added.

CLAIM REJECTIONS

Claims 1 and 2 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. Applicant has amended claim 1 to correct the insufficient antecedent basis for the limitations "said second longitudinal portion" and "said first longitudinal portion" so that this rejection is obviated.

Claims 1-4, 8 and 9 were rejected under 35 U.S.C. §102(b) as being anticipated by Vrba, U.S. Patent No. 6,168,621. Claims 5 and 6 were rejected under 35 U.S.C. §102(b) as being anticipated by Marshall et al., U.S. Patent No. 5,609,605.

Applicant respectfully traverses the rejections under 35 U.S.C. §102(b) for the reasons set forth below.

Applicant has amended independent claim 1 to clarify that the invention is a cardiovascular stent and balloon assembly that includes a stent and a balloon, with the balloon comprising a first balloon portion having a first diameter when inflated and a second balloon portion having a second diameter when inflated, wherein the second diameter is greater than the first diameter. The balloon is disposed within the stent so that the first balloon portion is within the first longitudinal portion of the stent and the second balloon portion is within the

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invention, particularly as set forth in independent claims 1 and 3 and the claims depending therefrom. Vrba discloses a stent that has a balloon expanded portion and a self-expanding portion. The self-expanding portion is formed of a shape memory metal so as to enable self-expansion at body temperature upon release of the stent from its delivery catheter. After the

PAGE 16/25 * RCVD AT 2/6/2007 3:16:16 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-2/6 * DNIS:2738300 * CSID:6169885894 * DURATION (mm-ss):05-52

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catheter sheath has been retracted the self-expanding part or portion flares outwardly, and subsequently, the balloon expanding portion may be expanded by a balloon. There is no disclosure or suggestion in Vrba of using a balloon to expand the self-expanding portion of the stent.

In stark contrast to Vrba, the present claimed invention of independent claims 1 and 3 includes a stent that has two portions with different degrees of expandability, and a balloon disposed within the stent having two portions of different degrees of inflation. Thus, the stent may be positioned within the vessel and the balloon may then be inflated to expand both portions of the stent to their expanded state. The larger diameter or flange portion of the stent thus may be deployed or expanded via the same inflation process that expands the first, smaller, diameter portion of the stent. Not only does Vrba not disclose or suggest expanding the flared outward part of the stent via a balloon, Vrba teaches away from such a stent by disclosing the self-expansion of the self-expanding part and disclosing that a sheath of a delivery catheter is disposed around the self-expanding part to keep the self-expanding part from flaring outwardly until the stent is in the appropriate location, whereby the sheath may be retracted, and subsequently the balloon may be inflated. Thus, Vrba discloses a stent that requires a corresponding sheath and thus requires two distinct steps to deploy the stent, namely, retracting the sheath from the self-expanding portion of the stent and then subsequently inflating the balloon to expand the balloon expandable portion of the stent. Moreover, there is no disclosure or suggestion in Vrba of a balloon that has different portions that have different expanded diameters, so that the portion with the larger diameter deploys one portion of the stent, while the balloon portion of the smaller diameter deploys another stent portion.

Therefore, Applicant respectfully submits that Vrba, either alone or in combination with any other reference of record, does not disclose or suggest the claimed invention of independent claims 1 and 3 and the claims depending therefrom. Reconsideration and withdrawal of the rejection of claims 1-4 is respectfully requested.

With respect to the rejection of independent claim 5, Applicant submits that Marshall et al. does not disclose or suggest the stent and balloon assembly of the claimed invention. Marshall et al. discloses a stent with a generally cylindrical balloon that is placed within two separate stents, whereby inflation of the balloon enlarges each respective stent or

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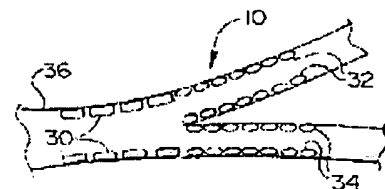
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stent section to its enlarged size. There is no disclosure in Marshall et al. of a stent having a distal stent portion and proximal stent portion with different degrees of expansion, and whereby a proximal balloon portion expands the proximal stent portion to form a flange for engaging an interior wall of a vessel. To the contrary, Marshall et al. discloses a single cylindrical balloon that fits within different diameter cylindrical stents or stent sections.

Therefore, Applicant respectfully submits that Marshall et al., either alone or in combination with any other reference of record, does not disclose, teach or suggest the claimed invention of independent claim 5 and the claims depending therefrom. Reconsideration and withdrawal of the rejection of claims 5 and 6 is respectfully requested.

With respect to independent claim 7, Applicant notes that there is no specific rejection of independent claim 7 in the Office Action. However, Applicant notes that dependent claim 8, which depends on independent claim 7, was rejected under §102(b) as being anticipated by Vrba. Accordingly, Applicant has treated independent claim 7 as if it were also rejected under 35 U.S.C. §102(b) as being anticipated by Vrba. Applicant submits that Vrba does not disclose or suggest the method of independent claim 7. There is no disclosure or suggestion in Vrba of inserting a first stent in an inlet portion of a bifurcation and in a first outlet portion of the bifurcation, and expanding the first stent to support at least a portion of the inlet portion and the outlet portion, and inserting a second stent through a wall of the first stent so that (1) a distal portion of the second stent is located in the other outlet portion, and (2) a proximal portion of the second stent is located within the first stent, such that expansion of the distal portion of the second stent supports the other outlet portion, while expansion of the proximal portion of the second stent causes the proximal portion to engage the inner wall of the first stent in a flange-like arrangement. To the contrary, Vrba discloses a bifurcated stent that has three segments or components, a main trunk and two branches, as shown in Figures 7-10 of Vrba (Fig. 8 of Vrba is reproduced to the right). As can be seen in Figure 8 of Vrba, there is no insertion of a second stent through a wall of a first stent. Nor is there any expansion of a proximal portion of a second stent so that the proximal portion of the second stent engages the inner wall of the first stent in a flange-like arrangement.

Fig. 8



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Therefore, Applicant respectfully submits that Vrba, either alone or in combination with any of the cited art of record, does not disclose, teach or suggest the claimed invention of independent claim 7 and claims depending there from. Reconsideration and withdrawal of the rejection of independent claim 7 is respectfully requested.

Accordingly, Applicant respectfully submits that neither Vrba or Marshall et al., either alone or in combination with one another or with any other prior art of record, disclose, teach, suggest the balloon and stent assembly or method of the present invention, particularly as set forth in independent claims 1, 3, 5 and 7 and in the claims depending therefrom. Reconsideration and withdrawal of the rejections of claims 1-8 is respectfully requested. Because new claims 10-18 are dependent on the independent claims 1, 3, 5 and 7, Applicant submits that new claims 10-18 are also in condition for allowance. Applicant further submits that new claims 19-23 are also in condition for allowance.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant is submitting herewith a Supplemental Information Disclosure Statement that cites items for consideration by the Examiner. Applicant respectfully requests that the Examiner consider the information cited in the Supplemental Information Disclosure Statement and return an initialed copy of the Statement to confirm the Examiner's consideration of the cited information. In accordance with 37 CFR § 1.97(c)(2), the fee of \$180 is also included to cover the fee set forth in 37 CFR § 1.17(p).

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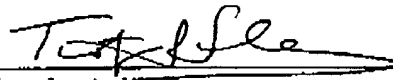
Claims 1-8 and 10-23 are pending in the application. Applicant respectfully submits that claims 1-8 and 10-23 are in condition for allowance and a notice to that effect is earnestly and respectfully requested.

Respectfully submitted,

JIHAD A. MUSTAPHA

By: Van Dyke, Gardner, Linn & Burkhart, LLP

Date: February 6, 2007.



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